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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,013	11/16/2001	Shui-on Leung	IMMU:014US2	7681

37013 7590 03/29/2010

ROSSI, KIMMS & McDOWELL LLP.
20609 Gordon Park Square, Suite 150
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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
03/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomail@rkmlegalgroup.com

Office Action Summary	Application No.	Applicant(s)	
	09/988,013	LEUNG ET AL.	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,31,32 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-29, 31-32 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *90c (requirement for information)*.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09988013	11/16/01	LEUNG ET AL.	IMMU:014US2

ROSSI, KIMMS & McDOWELL LLP.
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Ashburn, VA 20147

EXAMINER	
DAVID J. BLANCHARD	
ART UNIT	**PAPER**
1643	20100322

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

REQUIREMENT FOR INFORMATION UNDER 37 CFR § 1.105
Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. See MPEP §§ 704.10 [R-2] and 704.11.

This request is being made for the following reasons:
Applicant is claiming methods of designing the amino acid sequences of a humanized antibody and methods for producing the humanized antibody, wherein the exemplary antibody of the instant applictaion is the murine LL2 antibody. The IDS filed 2/20/04 cites Belise et al. Proc. of the Amer. Assoc. for Can. Res. 34:481, #2873, March 1993 (reference A5), however, it has come to the attention of the examiner that abstract #2872 (Leung et al), not cited on the IDS filed 2/20/04 appears to be more relevant to the instant application and claimed subject matter. Abstract #2872 generally discloses the humanization of the murine LL2 antibody, however, the abstract appears to correspond to a more detailed post-filing publication on the humanization of LL2, e.g., Leung et al. Mol. Immunol. 32(17/18):1413-1427, 1995 (cited on PTO-892 mailed 2/20/04), which shares the same authors and was supported by the same NIH grant CA 39841. Thus, the record suggests the applicant and the assignee of this application likely have access to information relevant to the issue of patentability and thus, shows the need for information in addition to that already submitted by the applicant.

With respect to the prior art of Leung et al. Proc. of the Amer. Assoc. for Cancer Research, vol. 34, pg. 481, abstract 2872, March 1993;
(1) Does the Leung et al 1995 publication correspond to work earlier presented in abstract #2872 at the Proc. of the Amer. Assoc. for Cancer Research meeting held March 1993?
(2) Was the Leung et al abstract (#2872) a poster presentation or a slide presentation?
(3) What additional information was displayed/presented that is not present in the printed Leung et al abstract #2872, e.g, what human heavy and light chain frameworks were selected and used for LL2 humanization, which LL2 murine framework residues were retained in the humanized antibody, ect?
(4) If a poster presentation, what was the full/complete content of the presentation/display? Was the poster displayed where persons of ordinary skill in the art could see it and not precluded from copying? What was the length of time of the poster presentation? Were any copies of the poster presentation disseminated and/or indexed in a library or database?
(3) If a slide presentation, what is the full/complete content of the presentation/slides? Were the slides printed and pasted onto poster boards and if so, what is the length of time of the display? Were the slides presented transiently and if not, what was the length of time that the sldies were presented? Were there any confidentility restrictions and were there any restrictions to copying?
(4) Are copies of the poster and/or slides presented at the March 1993 Proc. of the Amer. Assoc. for Can. Res. Conference available?

If available, please provide copies.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643

DETAILED ACTION

1. Claims 1-27, 30 and 33-43 are cancelled.
Claims 44-47 have been added.

2. Claims 28-29, 31-32 and 44-47 are pending and under consideration.

3. This Office Action contains New Grounds of Rejections.

Request for Information Under 37 CFR 1.105

4. A request for information under CFR 1.105 accompanies this Office Action. Please see attached pages.

Objections/Rejections Maintained and New Grounds of Rejections

Specification

5. The objection to the disclosure at par. [0001] as requiring updating is maintained in part and made again.

The reply filed 12/28/09 amends par [0001] at pg. 1 of the specification to indicate that the instant application is a continuation of US Application No. 08/289,576 (consistent with the record, e.g., appeal brief filed 3/31/08 and BPAI decision mailed 3/13/09). This has been fully considered and is found persuasive. However, the objection is being maintained in that applicant has not updated the status of USSN 09/741,843 as requested in the previous Office Action, "Additionally, applicant should update the status of US Application No. 09/741,843 filed December 22, 2000, which is now abandoned.". See 37 C.F.R. 1.121.

Additionally, the amendment to the specification filed 12/28/09 indicates "…and claims benefit of priority to, U.S. Serial No. 09/127,902 filed on August 3, 1999, filed on August 3, 1999, now U.S. Patent No. 6,187,287….", which is duplicative in that "filed August 3, 1999" is presented twice and also appears to be inaccurate as the PTO records indicate that USSN 09/127,902 was filed on August 3, 1998.

Further, the amendment filed 12/28/09 includes the phrase "and claims benefit of priority to...", which is grammatically incorrect. Consider revising the phrase to 'and claims benefit of..' or 'and claims priority to…'.

Appropriate correction is required.

Priority

6. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In view of the decision by the Board of Patent Appeals and Interferences mailed 13 March 2009, the disclosure of the prior-filed application, Application No. 08/289,576, filed August 12, 1994, provides adequate written descriptive support for the claimed invention in the manner provided by the first paragraph of 35 U.S.C. 112. Accordingly, the effective filing date of the instant claims is deemed to be August 12, 1994, the filing date of Application No. 08/289,576.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The rejection of claims 28-29, 31-32 and now applied to newly added claims 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al (WO 94/09136, published 4/28/1994) is maintained.

The replies filed 10/23/2009 and 12/28/2009 supplies a Rule 131 Declaration with evidence showing that applicant had reduced to practice the present invention prior to the effective date of the cited Harris et al reference. The Declaration under 37 CFR 1.131 filed on 10/23/09 and 12/28/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the applied reference because the Declaration is not executed by one of the named inventors, e.g., Dr. Shui-On- Leung, and it has not been shown that Dr. Hans Hansen is the sole inventor of the claimed subject matter. MPEP 715.04(I)(B) states:

> An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection.

Thus, the rejection of claims 28-29, 31-32 and 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al is maintained.

9. Claims 44-47 under 35 U.S.C. 102(b) as being anticipated by Adair et al (WO 91/09967, published 7/11/1991).

Adair et al teach a method of designing humanized heavy and light chain variable domain amino acid sequences of murine monoclonal antibody B72.3 comprising comparing the light and heavy chain variable domain sequences of B72.3 with the light and heavy chain sequences of two or more human antibodies (e.g., those in Kabat), wherein the human REI light chain frameworks are selected and the human EU heavy chain frameworks are selected for FR1, FR2 and FR3 and a human consensus heavy chain FR4 was selected and the selected human frameworks are incorporated with the corresponding light and heavy chain CDRs of B72.3 and the light chain mouse residue at position 48 (2 amino acids from CDR2) and the heavy chain mouse residues at position 73, which is close to both CDRs 1 and 3 and could have a detrimental effect on antigen binding were retained in the humanized B72.3 antibody (i.e., residues predicted to have contacts with the CDRs and within a 4.5 Angstrom radius of any atoms within the

CDRs). Adair et al also teach preparing the DNA sequences encoding the designed humanized B72.3 light and heavy chain variable domain amino acid sequences, operably incorporating the prepared humanized light and heavy chain variable domain sequences into expression vectors comprising the human light constant region and the human IgG1 constant region, transfecting host cells with the light and heavy chain vectors and culturing the cells under conditions to produce the humanized B72.3 antibody that binds mucin (see entire document, particularly Example 3 and pp. 10-15).

Thus, Adair et al anticipates the claims.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643